DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 596-7700
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May 27, 2003

WARNING LETTER

NWE-18-03W

VIA FEDERAL EXPRESS

William J. Keefe, Owner
Carneys Drug
32 Main Street
Rochester, New Hampshire 03867

Dear Mr. Keefe:

On August 28, 2002, FDA Investigator John S. Hartford of the New England District Office conducted an inspection of your facility. A representative from the New Hampshire State Board of Pharmacy accompanied Mr. Hartford on this inspection. The inspection disclosed that your firm compounds Fentanyl oral lozenges ("lollipops") ranging in strength from 800 mcg to 4000 mcg.

Although in the FDA Modernization Act of 1997, Congress had provided certain conditions under which compounded drugs could be exempt from particular requirements of the Federal Food, Drug, and Cosmetic Act (the Act), as a result of a Supreme Court ruling last year, those exemptions are no longer available for compounded drugs.

Because of the Supreme Court decision, FDA determined that it needed to issue guidance to the field and compounding industry on what factors the agency will consider in exercising its enforcement discretion regarding pharmacy compounding. This guidance issued on June 7, 2002 in the form of Compliance Policy Guide (CPG), Section 460.200.

As a result, the agency now applies its longstanding policy to recognize and exercise its enforcement discretion for extemporaneous compounding, where reasonable quantities of drugs are manipulated upon receipt of valid prescriptions from licensed practitioners

for individually identified patients. One factor that the agency considers is whether or not there is any documentation that demonstrates a medical need for particular patients for a specific variation between a commercially available drug product and compounded drug product. During the inspection of your firm, it was disclosed that your Fentanyl oral lozenge products have been compounded in strengths varying from 800 mcg to 4000 mcg. The commercially available product is available in 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1200 mcg and 1600 mcg strengths. In the absence of any documentation of medical need for particular patients for particular variations between the commercially available Fentanyl "lollipop" and your compounded Fentanyl "lollipop" drug products, such compounding would essentially constitute copying of a commercially available drug. The Agency would not consider this activity to be consistent with the regular course of a pharmacy dispensing drugs at retail.

In addition, the agency remains seriously concerned about the public health risks associated with the compounding of Fentanyl "lollipops" that are dispensed without the labeling and other packaging and patient safety features required by FDA for the FDA approved product. The inspection disclosed that your firm dispenses your Fentanyl "lollipops" in a pharmacy bag that is not child-proof. While certain warning information is provided in the labeling that accompanies your product, the product is not accompanied by such warnings and materials to assure restricted access to the product. The commercially available Fentanyl "lollipop" product is distributed with a child-resistant lock used to secure a storage space for the product in the patient's home. In addition, the commercially available product is dispensed with a portable locking pouch for storage of a small amount of the product for immediate use and a child-resistant temporary storage bottle that permits the patient to safely store it until it can be properly disposed of. Detailed patient labeling supplied with the commercially available product not only describes how to use these materials, it discusses how to store it in the home, the proper way to use it, how to dispose of any remaining product after use, and what to do if a child or an adult accidentally takes it. Our inspection disclosed that none of the safety measures mentioned above are provided to the patient by Carneys Drug at the time the compounded Fentanyl "lollipops" are dispensed to the patient. In addition, there is no identification of the drug substance or product on each compounded "lollipop," as required for the commercially available product, that would be needed in the event of an accidental exposure or overdose for which a poison control center would be contacted.

In light of the above, your compounded Fentanyl "lollipops", in dosage strengths ranging from 800-4000 mcg, are misbranded within the meaning of section 502(a) of the Act since its labeling is false and misleading in that it fails to reveal facts material with respect to consequences that may result from the use of the article under conditions of use prescribed in the labeling or under such conditions of use as are customary or usual. They are also misbranded within the meaning of section 502(f)(2) in that the labeling does not provide adequate warnings against use by children where its use may be dangerous to health in that it lacks information on the proper storage and disposal of the drug to avoid accidental ingestion by children. These products are further misbranded within the meaning of section 502(j) in that we believe they are dangerous to health when used in the manner prescribed in their labeling. In addition, if you are

compounding copies of commercially available drug products as described above, those products would be unapproved new drugs and would be in violation of section 505 of the Act.

The above violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that *all* your drug products are in compliance with federal laws and regulations. Failure to promptly correct all violations and prevent future violations may result in regulatory action without further notice, such as seizure and/or injunction.

Please notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct these violations, including an explanation of each step being taken to prevent the recurrence of the violations.

Please send the information and documentation outlined above to M. Patricia Murphy, Compliance Officer, U. S. Food and Drug Administration, One Montvale Avenue, 4th Floor, Stoneham, MA 02180.

Sincerely,

Gail T. Costello
District Director
New England District